REMARKS

Claim 1 is amended herein. Claims 2-36 are canceled and new claims 37-69 are added. Support is found, for example, in the original claims. No new matter is presented.

I. Information Disclosure Statement

The Examiner has returned initialed copies of the Information Disclosure Statements (IDS) filed on July 15, 2005, February 21, 2006, November 3, 2006 and November 15, 2007. However, the Examiner has not initialed all of the references listed on the PTO/SB/08 Forms submitted with the IDS's filed on July 15, 2005 and February 21, 2006. The Examiner also has not yet returned initialed copies of the PTO/SB/08 Forms submitted with the IDS's filed on February 11, 2008 and March 14, 2008.

Applicants respectfully request the Examiner to provide initialed copies of all outstanding forms and/or to provide an explanation as to why specific references are not initialed in the next Office Action.

II. Claim Objections

In paragraph 1 of the Office Action, claims 9-12, 21-24 and 33-36 are objected to under 37 C.F.R. § 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the Examiner states that claims 9-12, 21-24 and 33-36 have not been further treated on the merits.

Claims 9-12, 21-24 and 33-36 are canceled herein thereby rendering the objection as to these claims moot.

Accordingly, Applicants respectfully request withdrawal of the objection to claims 9-12, 21-24 and 33-36.

III. Response to Claim Rejections under 35 U.S.C. § 101 and 35 U.S.C. § 112, 2nd paragraph

In paragraph 3 of the Office Action, claims 13-20 are rejected under 35 U.S.C. § 101 because the claimed recitation of a use, without setting forth any steps involved in the process, is said to result in an improper definition of a process, i.e., to result in a claim which is not a proper process is said to claim under 35 U.S.C. § 101.

In paragraph 4 of the Office Action, claims 13-20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Per the Examiner, it is unclear what Applicant intends by the word "use" as to whether the claims are product or process claims.

Claims 13-20 are canceled herein, thereby rendering the rejections moot. Accordingly, Applicants respectfully request withdrawal of the §101 and §112, second paragraph rejections of claims 13-20.

IV. Response to Claim Rejections under 35 U.S.C. § 112

A. In paragraph 5 of the Office Action, claims 5-7, 17-19 and 29-31 are rejected under 35 U.S.C. § 112, second paragraph. The Examiner states that DCPP is not a carbostyril derivative as is required in claims 4, 16 and 28 and therefore claims 5, 17 and 29 lack antecedent basis in claims 4, 16 and 28, respectively. According to the Examiner, claims 6-7, 18-19 and 30-31 depend from claim 5, 17 and 29 respectively, and therefore the issues with claims 5, 17 and 29 are also contained in claims 6-7, 18-19 and 30-31 due to their dependence from rejected claims.

Claims 5-7, 17-19 and 29-31 are canceled herein, thereby rendering the rejection moot.

Accordingly, Applicants respectfully request withdrawal of the rejection.

B. In paragraph 6 of the Office Action, claims 13-20 and 25-32 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while said to be enabling for treating depression and major depressive disorder, allegedly does not reasonably provide enablement for treating other disorders known to man.

Claims 13-20 and 25-32 are canceled herein, thereby rendering the rejection moot.

The present claims recite the term "mood disorders", which is specifically defined in medical text books and lists of medical disorders, such as the "Diagnostic and Statistical Manual of Mental Disorders" (DSM-IV) of the American Psychiatric Association or the International Classification of Diseases (ICD-10) of World Health Organization (WHO). "Mood disorders" mean that some disabilities occur in life such as persistence of depressive mood or persistence of abnormal mood elevation. The criteria were set from the standpoint that disorders should be diagnosed by symptoms and not consider causes of the disorders. For example, depression does not always develop by only one of the causes of the disorder. Accordingly, the classification was formulated based on a concept such that "it is reasonable to classify mental diseases according to their symptoms." Thus, "mood disorders" does not mean disorders (e.g., the disorders claimed in the present application *per se)* themselves, but defines the symptoms that appear in many disorders.

As mentioned above, the original specification on pages 69 to 71 at the time of the filing date discloses a tail suspension test, which is a kind of an antidepressant animal model test. Such an animal model shows symptoms defined by mood disorders. It is understood that a synergetic effect was exerted when citalopram and aripiprazole are used in combination in the test. Therefore, the term "mood disorders" in the claims is sufficiently supported by Examples of the

present application. Based on the knowledge and skill in the art, the nature of the art, the description and the working examples provided in the present specification, one of ordinary skill in the art would readily be able to practice the claimed invention.

C. In paragraph 16 of the Office Action, claims 1-8, 13-20 and 25-32 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. According to the Examiner, the present claims drawn to a "carbostyril derivative" and to a "metabolite of aripiprazole" do not sufficiently define the compounds of the invention.

Claims 1-8, 13-20 and 25-32 are canceled herein, thereby rendering the rejection moot.

Accordingly, Applicants respectfully request withdrawal of the rejection.

V. Response to Claim Rejections under 35 U.S.C. § 102

In paragraph 18 of the Office Action, claims 1-3, 6, 8, 13-15, 18, 20, 25-27, 30 and 32 are rejected under 35 U.S.C. § 102(b), as being anticipated by Wong et al (U.S. 2002/0156067 A1).

Applicants respectfully traverse the rejection as it might be applied to the present claims.

The present invention is directed to a pharmaceutical composition comprising (a) a compound selected from aripiprazole or a metabolite of aripiprazole wherein the metabolite of aripiprazole is selected from the group consisting of dehydroaripiprazole, DM-1458, DM-1451, DM-1452, DM-1454 and DCPP in combination with (b) at least one serotonin reuptake inhibitor selected from the group consisting of fluoxetine, duloxetine, venlafaxine, milnacipran, citalopram, fluvoxamine, paroxetine, sertraline, escitalopram and salts thereof. The present invention is also directed to a method of treatment of mood disorders comprising administering an effective amount of the composition of the present invention.

US 2002/0156067A1 discloses a composition comprising a combination of a norepinephrine reuptake inhibitor with a neuroleptic agent. Duloxetine, venlafaxine and

milancipram are described as examples of a norepinephrine reuptake inhibitor. Aripiprazole is described as an example of a neuroleptic agent. However, Wong et al does not identically disclose the presently claimed invention as required for anticipation under 35 U.S.C. § 102. Specifically, Wong et al does not disclose an embodiment which includes all elements of the present claims. That is, Wong et al does not disclose specific combinations of aripiprazole and a norepinephrine reuptake inhibitor and neuroleptic agents. In order to arrive at the presently claimed invention, one would have to pick and choose among the listed compounds which are described as norepinephrine reuptake inhibitors and also among the listed neuroleptic agents. Such picking and choosing is not permissible in an anticipation rejection. Additionally, the number of potential combinations of the disclosed norepinephrine reuptake inhibitors and neuroleptic agents is in the hundreds, perhaps thousands, and Wong et al does not express a clear preference for any of the compounds in the lists of norepinephrine reuptake inhibitors and neuroleptic agents of the reference that would meet the requirements of the present claims. Accordingly, Wong et al does not describe an embodiment with sufficient specificity to anticipate the claims of the present invention within the meaning of 35 U.S.C. § 102.

Since Wong et al does not disclose an identical composition, it cannot be said that it inherently has the same properties and could be used for the method of treating mood disorders as recited in the present claims.

Further, Wong et al does not disclose that the combination of aripiprazole with a SRI exerts excellent treating or improving effects. Therefore, the combination can be used at a lower dose, thus, less side effects, and is excellent in safety. Wong et al does not disclose nor suggest that the combination may have the above advantages. Thus, the present invention is not anticipated nor rendered obvious over Wong et al.

As noted at pages 69 to 71 of the present specification, a tail suspension test is disclosed which is an antidepressant animal model test. Based on the data provided in the specification, it is understood that a synergistic effect is exerted when citalopram and aripiprazole are used in combination and thus the amount used of each ingredient can be decreased in case of their combined use. Therefore, the combination has less side effects and is excellent in safety. Thus, the present invention is neither anticipated nor rendered obvious by the cited reference. For this additional reason the present invention is patentable over Wong et al.

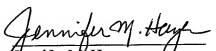
Accordingly, Applicants respectfully request withdrawal of the §103 rejection.

VI. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



Jennifer M. Hayes
Registration No. 40,641

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860
WASHINGTON OFFICE
23373
CUSTOMER NUMBER

Date: June 4, 2008